Complete Summary

GUIDELINE TITLE

Cross-sectional imaging in colorectal cancer.

BIBLIOGRAPHIC SOURCE(S)

Simunovic M, Stewart L, Zwaal C, Johnston M, Diagnostic Imaging Guidelines Panel. Cross-sectional imaging in colorectal cancer: recommendations report. Toronto (ON): Cancer Care Ontario (CCO); 2006 Apr 12. 19 p. [47 references]

GUIDELINE STATUS

This is the current release of the guideline.

Please visit the Cancer Care Ontario Web site for details on any new evidence that has emerged and implications to the guidelines.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Oncology
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the indications for ultrasonography (ultrasound), computed tomography (CT) scan, or magnetic resonance imaging (MRI) in patients with colorectal cancer:

- For the staging of a patient with newly diagnosed cancer
- To assess tumour response in patients undergoing chemotherapy or radiotherapy
- To detect disease recurrence in patients following curative treatment for cancer

TARGET POPULATION

Patients with colorectal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

1. Ultrasonography (ultrasound)
2. Computed tomography (CT)
3. Magnetic resonance imaging (MRI)

MAJOR OUTCOMES CONSIDERED

- Disease recurrence
- Survival
- Frequency of true- and false-positive tests
- Sensitivity and specificity of diagnostic tests
- Positive and negative predictive values

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search Strategy

An inventory of diagnostic imaging guidelines published in English after 1998 was completed by the Program in Evidence-Based Care (PEBC) in October 2003 and used to identify existing evidence-based guidelines. MEDLINE (Ovid–1980 to 23

September 2004), EMBASE (Ovid–1980 to 23 September 2004), and the Cochrane Databases of Systematic Reviews and Abstracts of Reviews of Effects (2nd Quarter 2004) were searched for meta-analyses, primary studies, and additional guidelines. Search strategies were modified for each database and disease site.

Searches of MEDLINE and EMBASE relied primarily on subject headings, with appropriate terms chosen for each database from the list in Appendix A in the original guideline document. Supplementary searches were conducted across disease sites for randomized trials and for studies reporting sensitivity/specificity; those searches used broader (i.e., less specific) search strategies in order to ensure that no relevant studies were missed. Titles, abstracts, full text, and keywords in the Cochrane databases of reviews were searched using text words such as ultrasound, computed tomography, magnetic resonance, cancer, and carcinoma.

Study Selection Criteria

Inclusion Criteria

Studies were included if they:

- Included patients with confirmed cancer of the colon/rectum
- Evaluated ultrasound, computed tomography (CT), or magnetic resonance imaging (MRI)
- Reported data for disease recurrence, survival, frequency of the true- and false-positive tests for extent of disease, or sensitivity, specificity, positive predictive value or negative predictive value for extent of disease
- Were randomized trials, comparative cohort studies, case series (prospective or retrospective) with more than 12 consecutive patients, meta-analyses (published in English after 1998) of data from randomized trials, comparative cohort studies, or case series

Literature searches for primary studies were not restricted by language, but, because resources for translation were limited, evidence was abstracted only from English-language papers. Where evidence-based guidelines from the Program in Evidence-Based Care or other guideline developers existed, they were reviewed. These guidelines provide descriptive and interpretive summaries of the evidence, as well as recommendations based on evidence, values, and expert opinion. Clinical practice guidelines were eligible if they stated objectives or guideline questions, described the literature searched, and cited references for the evidence described.

Exclusion Criteria

- Letters, editorials, and meeting abstracts
- Studies that used follow-up results as a gold standard for the presence of metastatic disease, if the length of follow-up was greater than three months
- Studies using endoscopic ultrasound, which is not readily available in Ontario

NUMBER OF SOURCE DOCUMENTS

One practice guideline, and 33 case series were identified.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Research Coordinator extracted the following information from published reports eligible for inclusion in the systematic review:

- Recommendations and qualifying statements for evidence-based practice guidelines
- Survival and recurrence data for randomized trials
- Percent of cases categorized as true positive or false positive, sensitivity, specificity, positive predictive and negative predictive value, and proportion of patients with disease from case series

Where necessary, true-positive, false-positive, sensitivity, specificity, positive predictive value, and negative predictive value rates were calculated from data provided in primary reports, using the Predictive Value Calculator available on the Web at http://www.azzopardi.freeserve.co.uk/easycalc/Additions/predict.htm.

Sets of tables summarizing the available evidence were distributed for review to individual panel members according to their area of practice, along with copies of guidelines and primary study reports. The guideline authors did not pool data from individual studies, but published meta-analyses were considered with the other evidence.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This guideline is one of a set developed by the Program in Evidence-Based Care's (PEBC) Diagnostic Imaging Guidelines Panel, using methods adapted from the Practice Guidelines Development Cycle. These guidelines are intended to:

- Promote evidence-based practice
- Provide guidance to clinicians about which imaging techniques are the most appropriate to use in the management of their patients
- Provide information that is useful to those charged with planning for the number of imaging machines needed for patients with cancer in Ontario

Panel members included medical, radiation, and surgical oncologists, diagnostic radiologists, and methodologists. Prior to embarking on guideline development, the members disclosed information on potential conflict of interest. On reviewing that information, the panel found no areas of concern among the information provided by the panel members on the PEBC's standard conflict-of-interest form. Three panel members were investigators in trials of positron emission tomography (PET), but the panel decided that this was not in conflict with developing a guideline on computed tomography (CT), magnetic resonance imaging (MRI), and ultrasound. The lead author of this guideline report on imaging in colorectal cancer declared no conflicts of interest. The PEBC is editorially independent of Cancer Care Ontario and the Ontario Ministry of Health and Long-term Care.

The Diagnostic Imaging Guideline Panel:

1. Formulated a set of guideline questions relevant to cancer care in Ontario
2. Systematically reviewed existing evidence-based guidelines and evidence from primary studies

The Colorectal Working Panel:

1. Considered the quantity, quality, consistency, completeness, and relevance of the available evidence
2. Drafted recommendations
3. Consulted members of relevant PEBC Disease Site Groups for feedback

Evidence and expert opinion was considered in terms of whether imaging should be conducted (e.g., How often would diagnostic imaging with CT, MRI, or ultrasound revise staging in patients with cancer?) and then in terms of which imaging test would be most appropriate (e.g., Should ultrasound, CT, or MRI be used to detect liver metastases?). An informal consensus process was used to reach agreement on recommendations.

A focused external review process was planned for each document, utilizing the expertise of a small panel of experts. This review was obtained through a mailed survey consisting of items that addressed the quality of the draft report and recommendations and whether the recommendations should serve as a practice guideline.

Discussion and Consensus

CT and MRI are superior to ultrasound to detect liver metastases. For rectal cancer, and with regard to predicting tumour penetration through the rectal wall or positive nodes, transrectal ultrasound is slightly superior to CT or MRI, and equivalent to MRI with endorectal coil. This latter test is not widely available in Ontario. Of interest, it is likely that advances in technology will demonstrate

similar staging accuracy for routine MRI versus MRI with endorectal coil. For example, it is the practice of one of the guideline authors to recommend MRI with surface coil to assess T and N categorization for patients with rectal cancer. Moreover, it should be recognized that the results of any imaging test are influenced by the expertise of the involved clinicians (i.e., tests are operator dependent). This is likely truer for ultrasound than for CT or MRI. Thus, if transrectal ultrasound or cross sectional imaging determinations of T or N category will be used to make neoadjuvant therapy recommendations for patients with rectal cancer, individual centres may wish to compare the accuracy of such efforts using postoperative pathology staging. A positive test for regional lymph node involvement with tumour will be incorrect approximately 30% of the time with transrectal ultrasound, CT or MRI, and 20% of the time with MRI with endorectal coil. Potential involvement of the mesorectal margin by tumour can be assessed by CT or MRI.

There was no evidence to determine which imaging modality would be more useful in determining tumour response to therapy—therapy given preoperatively or for palliative purposes. There is evidence from a guideline produced by the Program in Evidence-based Care Gastrointestinal Disease Site Group (PEBC GI DSG) on the frequency of tests that should be performed on patients with varying stages of colorectal cancer presented in the guideline and recommendations. CT and MRI are equivalent in their ability to detect disease recurrence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

External Review

The draft report, with recommendations developed by a small panel of experts in oncology and radiology, was distributed with a 4-item survey in February and March 2006 for review as part of an external consultation process to a broader group of Ontario radiologists and oncologists. The external consultation included the 21 members of the provincial Gastrointestinal Cancer Disease Site Group and 20 other Ontario health care providers. Among the 17 respondents (42%), which included three radiologists, five surgeons, four radiation oncologists, and five medical oncologists, fifteen filled in the questionnaire and all provided written comments. Fourteen agreed that the methods used in the report development were appropriate and one neither agreed nor disagreed. Fourteen agreed with the

draft recommendations as stated, and that the recommendations should be approved as guidelines for practice, whereas two disagreed with those statements. Thirteen agreed that they would follow the recommendations of the report, one respondent neither agreed nor disagreed and two disagreed.

Report Approval Panel

The Program in Evidence-based Care (PEBC) Report Approval Panel (RAP) felt that guideline was well written. However, they also think that since the report drew heavily on PEBC Guideline 2.9 *Follow-up of Patients with Curatively Resected Colorectal Cancer*, an inclusion of a summary of the data of the randomized controlled trials and meta-analyses in the body of the report would help in understanding a fuller perspective of the recommendations. Therefore, the panel added another paragraph in the main text describing the randomized trials and meta-analysis included in the original PEBC guideline on patient follow-up.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Staging

- Prior to surgery, patients with colon cancer should have full staging including adequate images of the chest (i.e., an x-ray) and abdomen.
- Prior to surgery, patients with rectal cancer should have full staging including adequate images of the chest (i.e., an x-ray), abdomen and pelvis.
- Computed tomography (CT) or magnetic resonance imaging (MRI) scanning of the abdomen is recommended over ultrasound for detecting liver metastases.
- CT or MRI of the pelvis should be done to assess mesorectal margin status.
- If T and N category determinations will drive decisions on the use of neoadjuvant therapy, transrectal ultrasound or MRI with endorectal coil is recommended. Operator skill is more likely to influence the accuracy of transrectal ultrasound versus MRI with endorectal coil. It is likely that advances in technology will demonstrate similar staging accuracy for routine MRI versus MRI with endorectal coil.

Response

There is no evidence on the use of cross-sectional imaging to assess response to chemotherapy or radiotherapy in patients with colorectal cancer and so the following recommendations are expert and consensus based:

- It is reasonable to assess tumour response with CT or MRI, in addition to clinical examination and relevant blood tests, after every three cycles of therapy.
- In patients with locally advanced rectal cancer who receive preoperative therapies, further imaging with CT or MRI should be done 4-6 weeks after neoadjuvant chemoradiotherapy.

Follow-up

The imaging panel endorses the Program in Evidence-based Care (PEBC) Gastrointestinal Cancer Disease Site Group's (DSG's) recommendations for follow-up every six months for three years post-operation and annually thereafter for two years. The recommendations from this guideline are as follows:

- In patients who are at high risk of relapse (stages IIb and III disease) and who are fit and willing to undergo investigations and treatment:
    - Clinical assessment is recommended when symptoms occur or at least every six months for the first three years and yearly for at least five years.
    - During follow-up, patients may have blood carcinoembryonic antigen, chest x-rays, and liver ultrasound.
    - When recurrences of disease are detected, patients should be assessed by a multi-disciplinary oncology team including surgical, radiation, and medical oncologists to determine the best treatment options.
- In patients at high risk of relapse but who have co-morbidities that may interfere with prescribed tests or potential treatment for recurrence, or who are unwilling to undergo prescribed tests or potential treatment for recurrence:
    - Clinical assessments yearly or for symptoms suggestive of relapse.
- For patients at lower risk of recurrence (stages I and Ia) or those with co-morbidities impairing future surgery, only visits yearly or when symptoms occur are recommended.
- In all patients with resectable colorectal cancer (stages I, II, and III), colonoscopy before or within six months of initial surgery.

The diagnostic imaging panel, based on expert opinion, has made one modification to the above. Since ultrasound is typically unable to detect local recurrences of colon or rectal cancer, and since the intent of follow-up is to identify resectable recurrent disease, and recognizing that we have endorsed CT or MRI versus ultrasound in the detection of liver metastases at presentation, we further recommend the following:

- In patients who are at high risk of relapse (stages IIb and III disease) and who are fit and willing to undergo investigations and treatment:
    - Abdominal and pelvic CT or MRI yearly for at least five years. This would remove the need for one of the bi-annual ultrasounds of the liver in the first three post-operative years and ultrasounds of the liver in post-operative years four and five.

Diagnosing Recurrence

Evidence from three case series does not indicate a difference between CT and MRI for diagnosing recurrence in patients with a clinical suspicion of disease recurrence. Therefore, either diagnostic test can be recommended.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by one practice guideline and 33 case series.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of cross-sectional imaging in colorectal cancer

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The purpose of this guideline is to provide evidence-based recommendations on the use of diagnostic imaging for patients with colon and rectal cancer. However, other than one guideline for the follow-up of patients with curatively resected colorectal cancer, there is little high-quality evidence to help guide decisions for the varying aspects of patient care. Where existing high-quality guidelines were available, the guideline panel endorsed relevant recommendations. Where guidelines or strong evidence were not available, the panel considered current practice, underlying biologic principles, and expert clinical opinion in formulating the recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Simunovic M, Stewart L, Zwaal C, Johnston M, Diagnostic Imaging Guidelines Panel. Cross-sectional imaging in colorectal cancer: recommendations report. Toronto (ON): Cancer Care Ontario (CCO); 2006 Apr 12. 19 p. [47 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Apr 12

GUIDELINE DEVELOPER(S)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The Program in Evidence-based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

SOURCE(S) OF FUNDING

Cancer Care Ontario
Ontario Ministry of Health and Long-Term Care

GUIDELINE COMMITTEE

Diagnostic Imaging Guidelines Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: M. Simunovic; L. Stewart; C. Zwaal; M. Johnston

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Prior to embarking on guideline development, the members disclosed information on potential conflict of interest. On reviewing that information, the panel found no areas of concern among the information provided by the panel members on the Program in Evidence-based Care's (PEBC's) standard conflict-of-interest form. Three panel members were investigators in trials of positron emission tomography (PET), but the panel decided that this was not in conflict with developing a guideline on computed tomography (CT), magnetic resonance imaging (MRI), and ultrasound. The lead author of this guideline report on imaging in colorectal cancer (Marko Simunovic) declared no conflicts of interest. The Program in

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on October 28, 2006. The information was verified by the guideline developer on November 24, 2006.

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